K003320

MAY - 2 2001

NuMED, Inc.
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Contact Nichelle LaFlesh, Regulatory Affairs Mgr.

Date 25 April 2001

510(k)

SUMMARY

For The NuMED, Inc.

PTS

Sizing Balloon Catheter

SECTION SIX: 510(K) Summary

A. Trade Name: NuMED, Inc PTS Sizing Balloon Catheter

B. Common Name: Sizing Balloon Catheter

C. Device Class: II, 74MJN; 21 CFR 870.4550

D. Predicate Devices: Amplatzer Sizing Balloon

E. Description - The NuMED, Inc. **PTS™** Sizing Balloon catheter is a coaxial catheter for use in those patients with cardiovascular defects wherein accurate measurement of the defect is important to select the appropriately sized occluder device. The catheter inner and outer shafts are constructed of pebax tubing. The catheter features a proximal end bifurcate with two distinct luminal passages. The inflation lumen terminates into a distally mounted balloon made of pebax material. This balloon is of the non-compliant variety and will have a typical single wall thickness of **0.0004"**. This balloon is designed to insert through the smallest possible introduction sleeve. The distal lumen terminates at the tip of the catheter and will accept the passage of the appropriate guidewire. This lumen has two radiopaque platinum marker bands under the balloon shoulders for placement using fluoroscopy. Additionally, there are two radiopaque platinum marker bands 5mm on either side of the center of the balloon. The catheter is white in color and the balloon material is clear. The catheter balloon diameter is stamped onto the Y connector and the inflation extension is labeled with balloon diameter x balloon length x introducer size x shaft size x usable length x guidewire size and the catheter lot number. The catheter is packaged in a polyethylene loop and is double packed in two heat sealed Tyvek pouches. The **PTS** catheter is available in standard diameters from **20mm** to **40mm** in standard lengths of **3cm, 4cm, 5cm, and 6cm.** Guidewire size is standard **0.035"** with an introducer size of **8F or 9F**.

F. Indication - For use in those patients with cardiovascular defects wherein accurate measurement of the defect is important to select the appropriately sized occluder device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2001

Ms. Nichelle R. LaFlesh
Regulatory Affairs Manager
NuMed, Inc.
2880 Main St.
Hopkinton, NY 12965

Re: K003320
Trade Name: PTA-OS Sizing Balloon, Model 360
Regulatory Class: II
Regulation Number: CFR 870.4450
Product Code: MJN
Dated: January 31, 2001
Received: February 1, 2001

Dear Ms. LaFlesh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

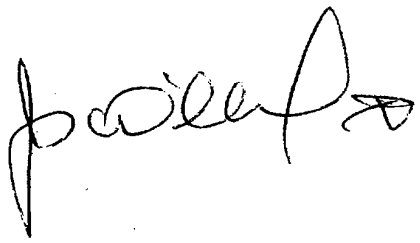
Device Name: **NuMED, Inc. PTS Sizing Catheter**

Indications For Use:

- For use in those patients with cardiovascular defects wherein accurate measurement of the defect is important to select the appropriately sized occluder device.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)